DEC - 8 2010

SECTION 6: 510(K) Summary

Submitter:	LeMaitre Vascular, Inc. 63 Second Avenue Burlington, MA 01803
Contact Person:	Vic Zhang Sr. Regulatory Affairs Specialist Phone: 781-221-2266 x162 Fax: 781-425-5049 Email: xzhang@lemaitre.com
Date Prepared:	November 12, 2010
Trade Name:	Pruitt Carotid Kit
Common Name:	Carotid Kit
Classification Name:	N/A
Predicate Device:	Pruitt F3 Carotid Shunt (K051067) Peripatch Biologic Patch (K040835)
Device Description:	The Pruitt Carotid Kit is a convenience kit composed of Pruitt F3 carotid shunt and XenoSure (Peripatch) biologic patch.
Intended Use:	The Pruitt F3 carotid shunts are indicated for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries. The size 8 French Shunt is intended for use on those patients whose vasculature is too small to accommodate a size 9 French Shunt. The patch is intended for use as a surgical patch material for: cardiac and vascular re-construction and repair, soft tissue deficiency repair and reinforcing the suture line during general surgical procedures.
Summary of Technological Characteristics:	The Pruitt Carotid Kit is a convenience kit composed of the Pruitt F3 carotid shunt and XenoSure (Peripatch) biologic patch.
Summary of Product Testing:	N/A
Conclusion:	LeMaitre Vascular has demonstrated that the Pruitt Carotid Kit is substantially equivalent to the predicate devices based on its indications for use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LeMaitre Vascular Inc.
c/o Vic Zhang
Sr. Regulatory Affairs Specialist
63 2nd Ave.
Burlington, MA 01803

DEC - 8 2010

Re: K103356
Trade/Device Name: Pruitt Carotid Kit
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: MJN, FTM
Dated: November 12, 2010
Received: November 16, 2010

Dear Mr. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5: INDICATION FOR USE STATEMENT

510(k) Number (if known): K103356

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Device Name: Pruitt Carotid Kit

Indications for Use:

For Pruitt F3 Carotid Shunts:

The Pruitt F3 carotid shunts are indicated for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries. The size 8 French Shunt is intended for use on those patients whose vasculature is too small to accommodate a size 9 French Shunt.

For XenoSure Biologic Patch:

The patch is intended for use as a surgical patch material for: cardiac and vascular re-construction and repair, soft tissue deficiency repair and reinforcing the suture line during general surgical procedures.

Prescription Use____X____ and/or Over-The Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE ID NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103356